# DATA EVALUATION RECORD -SUPPLEMENT

PARAQUAT DICHLORIDE

Study Type: §83-5; Combined Chronic Toxicity/Carcinogenicity Study in Rats

Work Assignment No. 3-1-88 M (MRID 40218001)

Prepared for
Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Pesticide Health Effects Group
Sciences Division
Dynamac Corporation
1910 Sedwick Rd, Bldg. 100, Ste. B
Durham, NC 27713

Primary Reviewer:
Ronnie J. Bever Jr., Ph.D. Signature: _____
Date: _____

Secondary Reviewer:
Stephanie E. Foster, M.S. Signature: _____
Date: _____

Program Manager:
Mary L. Menetrez, Ph.D. Signature: _____
Date: _____

Quality Assurance:
Steven Brecher, Ph.D., D.A.B.T. Signature: _____
Date: _____

Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel.

EPA Reviewer: Kimberly Harper Signature: _____
Registration Action Branch 2, Health Effects Division (7509C) Date_____
Work Assignment Manager: Ghazi Dannan, Ph.D. Signature: _____
Registration Action Branch 3, Health Effects Division (7509C) Date_____

Template version 11/01

DATA EVALUATION RECORD - SUPPLEMENT See TXR# 006652 for previous review.

This supplement contains:
-New Cover page
-New Executive Summary
-Revised classification statement

STUDY TYPE: Combined chronic toxicity/carcinogenicity (diet)- rats; OPPTS 870.4300 [§83-5]; OECD 453.

PC CODE: 061601 DP BARCODE: D321791
TXR#: 0053747

TEST MATERIAL (PURITY): Paraquat dichloride (>=98% a.i.)

SYNONYMS: 1,1'-dimethyl-4,4'-bipyridinium dichloride

CITATION: Toyoshima, S., R. Sato, M. Kashima, *et al* (1982) AT-5: Chronic toxicity study result - 104 week dosing study in rat. Nippon Experimental Medical Research Institute, Japan. Laboratory Project ID.: None, March 10, 1982. MRID 40218001. Unpublished.

SPONSOR: Asahi Chemical Industries Company, Ltd., Japan

EXECUTIVE SUMMARY: In this combined chronic toxicity/carcinogenicity study (MRID 40218001), paraquat dichloride (>=98% a.i.; Lot #: 540108) was administered in the diet to 50 Wistar rats/sex/dose at nominal concentrations of 0, 6, 30, 100, or 300 ppm (equivalent to 0/0, 0.25/0.30, 1.26/1.50, 4.15/5.12, and 12.25/15.29 mg/kg/day in males/females) for up to 104 weeks. Additionally 12 rats/sex/dose were treated similarly, and 6 rats/sex/dose were sacrificed at Weeks 26 and 52.

No adverse, treatment-related effects were observed on body weight, body weight gains, food consumption, or on any ophthalmoscopic examination, hematological, clinical chemistry, or urinalysis parameters, organ weights, or gross and histological pathology.

Increased mortality was observed in the 300 ppm males (incr 26%) and females (incr 10%). In moribund animals, decreased spontaneous mobility, loss of coat luster, and piloerection were noted.

**The LOAEL is 300 ppm (equivalent to 12.25/15.29 mg/kg/day), based on mortality. The NOAEL is 100 ppm (approximately equivalent to 4.15/5.12 mg/kg/day).**

At the doses tested, there was no treatment-related increase in tumor incidence when compared to controls. Dosing was considered adequate based on decreases in survival in both sexes.

This study is **acceptable/guideline** and satisfies the guideline requirement for a chronic/ carcinogenicity study (OPPTS 870.4300; OECD 453) in rats.

COMPLIANCE: A signed and dated Data Confidentiality statement was provided. A GLP statement was provided stating that the submitter does not know if this is a GLP study. Signed and dated Quality Assurance and Flagging statements were not provided; however, the study was conducted prior to the adoption of Good Laboratory Practice standards (40 CFR Part 160; November 29, 1983).